DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 19 2002

Peter Barton Hutt
Sarah E. Taylor
Covington and Burling
1201 Pennsylvania Avenue, N.W.
P.O. Box 7566
Washington, D.C. 20044

Re: Docket No. 78N-0038
Comment No. C105

Dear Mr. Hutt and Ms. Taylor:

This letter concerns your comments dated July 18, 1990, filed in support of a citizen petition (CP) filed by BASF AG on May 30, 1989. The petition is filed under Docket No. 78N-0038 in the Dockets Management Branch.

Since your letter was submitted, the agency has informed you and other interested parties that it was developing a process by which drugs without any marketing experience in the United States could become eligible for consideration in the agency's over-the-counter (OTC) drug review. We are pleased to inform you that the process is now being implemented.

This process is described in a final rule entitled "Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded," which was published in the Federal Register of January 23, 2002,(67 FR 3060). A copy is enclosed for your information. This final rule is effective on February 22, 2002.

The final rule requires the submission of a Time and Extent Application (TEA) (see § 330.14(c)) to request consideration under the OTC drug review. The required information and format for a TEA are set out in the final rule (see § 330.14(c)). Three copies of the TEA are to be submitted to the Central Document Room (see § 330.14(d)).

We have notified BASF AG that if they wish to pursue inclusion in the OTC drug monograph system of an OTC drug product or active ingredient that was the subject of their CP, to please submit a TEA in the required format. We do not intend to take further action on their CP.

As stated in comment 20 of the final rule that established the TEA process, the agency will give priority to TEA's associated with pending CP's if those CP's are converted to TEA's

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that are submitted within 120 days after publication of that final rule. We hope this information will be helpful.

Sincerely yours,

Dennis E. Baker
Associate Commissioner
for Regulatory Affairs

Enclosure

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 4-26-02

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 78N-0038

TO: Dockets Management Branch, HFA-305

[X] The attached material should be placed on public display under the above referenced Docket No.

[X] This material should be cross-referenced to Comment No. C105

Charles J. Ganley, M.D.

Attachment